Compliance and Culture: How Design and Approach Can Help Support Clinical Trial Billing

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Essential Building Blocks for a Strong Billing Compliance Culture

- Defined roles with functional reporting relationships
- Outlined research finance business operations
- Training and verification of clinical research billing competency
- Tracked metrics with self monitoring and independent auditing
Evaluating Current State

Evaluate Current State of Your Program

- Calculate the revenue cycle integrity
- Analyze the types of research in the portfolio
- Validate regulatory review that impacts billing processes
- Determine and document billing process functions
- Assess the personnel necessary to complete the business operations
- Track accounts receivable from research
Calculate Revenue Cycle Integrity

- Understand the business functions by evaluating revenue cycle
  - Coverage Analysis
  - Budgeting and Contracting
  - Charge Segregation
  - Invoicing to Sponsors
  - Reconciliation of Accounts Receivable
  - Payer Management Controls
  - Denial and Appeals Management
  - Write Offs

Types of Research in the Portfolio

- Sponsored Drug Clinical Trials
- IDE
- PI
- NCTN (Cooperative Group)
- Investigator Initiated
Validate Regulatory Review That Impacts Billing Processes

- Cost language review in consents for discrepancies against contract, budget and coverage analysis
- Eliminate language that violates the Medicare Secondary Payer Rule
- Inspect Medicare Advantage language in ICF or contract for drug trials
- Appraise different IRBs and templated cost language

Clinical Trial Billing Process

Coverage Analysis Review “Front End” Cycle
- Review protocol for feasibility
- Do a Qualifying Clinical Trial status
- Perform Coverage Analysis with validation
- Review draft budget, contract and consent
- National Guidelines for disease
- NCD’s and LCD’s applied

Document Review “Middle” Cycle
- Ensure Coverage Analysis guides all other documents
- Budget negotiation follows coverage analysis
- Contract language matches budget
- Consistency check confirming all documents prior to study opening

Patient On Study Review Back End
- Patient signs consent understanding financial implications
- Know every study and ever visit for each patient
- Segregate charges against Coverage Analysis and medical documentation
- Validate Coding rules and NCT# applied on claims
- Medicare Advantage review for drug clinical trials

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Assess The Personnel Necessary To Complete The Business Operations

- Examine the dynamics both with the upstream and downstream in regards to staffing resources and workload
- Inspect operational workflow with compliance in mind
- Construct an organizational structure with policies

Track Accounts Receivable from Research

- Treat research as a business
- Cover your costs adequately by doing a thorough coverage analysis as the starting point for every study
- Evaluate studies upon closure and final payment received
- Manage and track losses to know the cost of doing business
Build the Program

Development of Job Function

- Create job description(s) for positions (billing analyst, coverage analyst, etc.)

- Current team member or new hire:
  - **Seeking:**
    - Hospital and physician billing background
    - Coding background
    - Revenue cycle analyst
    - Analytical
    - Sense of urgency
Competency and Assessment

- Training Program
  - Conducting on-site training
  - Attending Conferences
  - Utilizing tools available via memberships/affiliations
- Building Competency
  - Yearly review of team member(s)
  - Develop checklist
  - Testing of competency
    - Observe, Review, Interact

Establish Billing Compliance Program

- Policies and Procedures
  - Establish core set of policies
    - Billing Compliance
    - Responsibilities of reviews
    - Coverage analysis method
  - Design billing compliance workflow
    - Develop with all stakeholders
  - Implement communication plan
  - Implement training program
Leverage Technology

- What Exists at the Site?
  - Electronic Medical Record
  - Policies and Procedures
  - Functionality
  - Work Queues or Reports available
  - Clinical Trial Management System
  - Policies and Procedures
  - Functionality
  - Regulatory System
  - eRegulatory
  - Electronic server storage
  - Paper files

Monitoring Plan

- Identify Billing Compliance Reviewer
  - Independent party to review
    - Preferred – Site Compliance Department
    - Billing compliance assessor
  - Quarterly Reviews – risk assessment
    - High enrolling studies
    - High volume investigators
    - New investigators
  - Review of first participant enrolled
    - Review entire workflow
Metrics Assessment

- What's important to your site?
  - Volume reviewed
  - Number of studies in compliance or not
  - Dollar impact
  - Fee estimate for non-compliance
- Manager review
  - Follow up training site, individuals, etc.
  - System failure or workflow needs improvement
- Document the review and work plan!

Elements for a Strong Program

- Clearly stated job description of role(s)
- Training program starts on hire date with a mentor assigned
- Open communication during development
- Buy-in of all stakeholders
  - Clinical, Finance, Departments, External Stakeholders (university, radiology, pharmacy, private practices), Compliance, Legal and C-Suite Executives
- Monitor plan and monthly reports
- Review, review and review
Discussion and Questions?

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